

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MORTON GROVE PHARMACEUTICALS, INC.)	
)	
)	
Plaintiff,)	
)	No: 08-CV-1384
v.)	
)	
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.,)	Judge Bucklo
)	Magistrate Judge Mason
)	
Defendant.)	
)	
)	

**MORTON GROVE’S REPLY IN SUPPORT OF ITS
MOTION TO STRIKE ALLEGATIONS AND DEFENSES
IN DEFENDANT’S ANSWER AND COUNTERCLAIM**

EXHIBIT INDEX

Exhibit A	Promotional Materials From Alliant Websites and <i>The Nit Picking News</i>
Exhibit B	NPA’s Response to Morton Grove’s Second Set of Requests to Admit No. 5
Exhibit C	Food and Drug Administration, Regulatory Procedures Manual, Chapter 4, Advisory Action, § 4-1-1

EXHIBIT A

The Nit Picking News

Vol. 1 No. 1

Sept/Oct 2006

NO NIT left behind

In a new twist on educational-reform mandates like the "No Child Left Behind" Law, *Pediculus humanus capitis* (the common head louse) could be coming out a front-runner. Once hard-lined about "no-nit" policies, schools are relaxing their standards to allow lice-infested children to remain or return to school in order to maintain attendance per requirements of federal law. Under the No Child Left Behind policy, student attendance is a major variable in determining the adequacy of statewide educational programs. Schools not meeting attendance criteria face sanctions that could include state takeovers of their schools. Thus, the entire system incentive seems to maximize attendance rather than prioritize health concerns... should we be concerned?

Since the late 1990s, groups like the American Academy of Pediatrics (AAP) have gone on record opposing no-nit policies, saying there is no medical justification for them. Similarly, the National Association of School Nurses (NASN) recommends the elimination of no-nit policies citing the following:

- Head lice are often misdiagnosed.
- Students sent home miss valuable in-school instruction.
- Removal of students for lice infestation can lead to teasing.¹

Growing opposition to the no-nit policies found effective substantiation when a study by Pollack et al in 2000 found that children with misdiagnosed infestations were more likely to be sent home than children with viable lice infestations. Surprisingly, physicians were least accurate in distinguishing nits from other material, such as dandruff and other debris. School nurses, while most accurate in diagnosing lice infestation, did not effectively distinguish live from extinguished infestations.²

Relaxation of no-nit policies has sparked opposition from the National Pediculosis Association (NPA). Founded in 1983, the NPA maintains that mechanical removal of lice eggs is the only safe and reliable way to end infestations. Also note that the NPA sells a trademarked nit-picking comb (LiceMeister®).

The American Head Lice Information Resource Center (AHLIRC) is lukewarm on the no-nit policy, stating, "We believe that school nurses should have some discretion in implementation. No child should be forced out of school for long periods because of a head lice infestation that won't go away despite a parent's best efforts."³

No, lice do not present a life or death situation (in most circumstances). But, they certainly can pose a public health concern, as they are easily transmitted by human contact or the close contact of clothing, such as coats or other personal items. Parents seem to be the most aggravated by the repealing of no-nit policies. The idea of lice sharing residence with the family, living in and dining on the children is a ghastly prospect to most responsible parents, and unfruitful efforts to eradicate this pesky visitor because of perceived non-cooperation from the schools is both monetarily and emotionally costly.

A recent article in the *Wall Street Journal* cited the opinions of several parents whose children had been infested and reinfested as a result of the new nit tolerance in the classroom. They agreed that the time and money spent to clear their child from infestations was more than a nuisance.⁴ (continued on Page 2)



At the heart of the no-nit controversy is the school nurse. The school nurse is the key facilitator of successful lice eradication and prevention programs. Nurses are in a position to most accurately diagnose, provide educational information and support to families, and advise school administration. Whether or not the school has a no-nit policy, the nurse must educate and re-educate the families about appropriate and effective treatment, and treatment compliance.

School nurse, Judy Magee, studied parental louse-treatment compliance of 27 families, a total of 119 children, and found the following:

- Over-the-counter lice control products containing pyrethrins or pyrethroids were used on over 90% of the children during the past year. Only 18% of the families surveyed used these products according to label directions.
- 23% of the children had been treated with (doctor-prescribed) Lindane Shampoo. Only one of the six families said they used Lindane as prescribed. Lindane Shampoo is indicated as a

second-line alternative to other treatments that have not eradicated head lice.

- 32% of the children were "treated" with dangerous "home remedies." One mother rubs Black Flag Roach Killer into her children's hair every day. Raid, flea soap, kerosene and/or the illegal roach product Chinese Chalk, were also used.
- One-third of U.S. adults read at or below the reading level of the instructions on the treatment product. One-quarter of the families surveyed could not read English.⁵

Educating parents regarding treatment and the need to follow up on and/or reiterate the importance of labeled use of pediculicides cannot be overstressed. The school nurse should provide a parental education booklet, outlining the school policy and effective treatment guidelines. Presentations at PTO meetings or on health days are also helpful in raising awareness. Talk to the children. Sometimes they listen better than their parents. Make sure the teachers are on board.

The keys to effective head lice eradication are:

- preparedness
- education
- compliance
- persistence

Initiatives by the government to assure success of the educational system (No Child Left Behind) and to enforce attendance policies are, for better or worse, well-meaning substitutes for responsible parental mandates for effective education. Growing support for a more relaxed no-nit policy has been adopted by leading lice experts across the country, with the caveat that a rational approach will include aggressive education of and participation by all parties involved to achieve a successful outcome—No Nit Left Behind.

LINDANE facts

- 4 minute application time¹²
- Non-flammable¹²
- Indicated for head lice and pubic lice^{12,13}
- Good cosmetic acceptability¹⁴
- Prescribed for over 50 years
- Number 1 prescribed product for head lice¹⁵
- "FDA has determined that lindane products have benefits that outweigh risks when used as directed. **Most serious adverse events reported in association with lindane products have been due to misuse.**"¹⁶

WARNINGS:

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following other skin conditions (eg, atopic dermatitis, psoriasis) and those who weigh <119 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Contraindications

Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

Proper Use

Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients (See DOSAGE AND ADMINISTRATION sections of the full prescribing information).

SURFING FOR safe answers

Internet Head Lice Treatments...Reality or Ripoff?

When a child has head lice or has been exposed to head lice, it is of utmost importance that a sound medical treatment plan be presented to parents. When clear-cut guidelines and treatment options are not made available, desperate, well-meaning parents turn to personal sources of information. This includes friends and acquaintances, surfing the internet for safe answers to "kill lice, not kids," or even asking the local beauty consultant for her favorite recipe, all of which can result in ineffective and often unsafe head lice treatment.

With internet information technology at our fingertips, we are inclined to take things into our own hands and, like the old adage, "We discover just enough to be dangerous." So how does one sift through the cyber-market to decide what is effective, safe, accepted, or supported by legitimate sources? First, look for legitimate websites; that is, sites of national lice organizations or medical sources. Be wary of sites that appear to sponsor a certain product, their bottom line is sales. See the list in this newsletter for examples of helpful websites.

Second, don't believe information just because you read it somewhere once. Substantiation for use of a certain pediculicide should come from several reputable sources. No good researcher draws definitive conclusions based upon one piece of evidence. This is especially true when it comes to medicating children, for whom safety should be the primary concern. It is precisely the safety issue that motivates parents to search for alternative delousing methods. Natural cures present an attractive substitute to soaking their child's head in insecticide. This is a commendable concern, but safe is not always effective. Soap and water are safe, but do not kill head lice. Effective treatment and safety must be a balanced approach. Let's take a look at some "alternative" lice treatments likely to show up on a Google "head lice" search.

Essential Oils: These include herbal extracts and homeopathic tinctures. There is no scientific evidence for the efficacy of

these products against adult lice or eggs, and they may contain substances that irritate the skin. Commonly used agents are extracts of paw paw, tea tree, thymol, rosemary, coconut, anise, and Ylang Ylang. One such product, Hair Clean 123 (Quantum, Inc., Eugene, Oregon) has been tested in clinical trial settings by researchers from the University of Miami and Hasdassah-Medical School, Jerusalem, Israel, with up to 93% treatment success.

Enzyme Treatments: Several commercial products claim to dissolve the "cement" that binds the nit to hair. This is a resistant bond to break, even with a diverse range of chemicals and certain efficacy has not been established. These are not endorsed by professionals in the treatment of head lice. Fairy Tales Lice Goodbye™ Mousse is an example. Vinegar has also been said to dissolve the nit/hair bond.

Suffocating Agents: Smothering lice has been a popular concept in "safe" delousing. Treating the hair with products like mayonnaise, olive oil or petroleum jelly have been purported to smother adult lice and eggs. It is recommended to leave these products on the hair for extended periods of time, and even then, their effectiveness on lice and eggs is questionable. Adult lice and eggs survive for many hours without breathing air. Additionally, rinsing these products out of the hair is very difficult.

A small study was undertaken by Harvard University School of Public Health wherein six live lice were submerged in olive oil for one and two hours. Those removed after one hour recovered, but two hours in olive oil resulted in death. The researchers stressed the preliminary nature of this experiment stating, "it would be an error to extrapolate from such an informal test...we do not recommend the use of olive oil as a treatment for head lice."⁶

Nonits® (Changes and Co.) is available as an olive oil-based solution or coconut oil-based shampoo. These also contain the essential oils of lavender and tea tree to prevent reinfestation and

of lice. (See INDICATIONS AND USAGE section of the full prescribing information.)

single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, and individuals with

itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo.

promote healing. The only evidence for efficacy for this product is the pilot study on 6 lice with olive oil at Harvard, however, the product seems to be favorably perceived by some organizations, including the New York Coalition for Alternatives to Pesticides (NYCAP).⁷

Dr. Andrew Weil, Founder and Director of the Program in Integrative Medicine (PIM) at the College of Medicine, University of Arizona, suggests a home-made treatment of vegetable oil, tea tree oil, rosemary, lavender and lemon. Dr. Weil recommends irritancy testing this remedy on the sensitive skin of the inside elbow for several hours before using the mixture on the head. Apply the mixture to the hair, wrap the head in a towel and leave for 1 hour, then shampoo.

Once again, there is no solid, consistent research evidence that oils, essential or otherwise, effectively treat lice infestations.

Antibiotics: Some physicians prescribe antibiotics for head lice infestation based upon a premise that has been established for body lice. The rationale is that antibiotic treatment kills the gut bacteria of the louse, leaving the insect unable to digest its blood meal, with ultimate death. In particular, the antibiotics Bactrim® or Septra® have been prescribed in this manner. This treatment methodology is not widely supported by public health specialists or pediculosis experts.

Heat or Cold: Using heat to kill lice and eggs is not 100% foolproof and can be dangerous. Standard protocols for effective use (treatment times, temperature, distance from the head) of blow dryers, curling irons and hair straightening devices are not established. Prolonged exposure to heat from these devices may scald the hair and scalp. It is also difficult to apply heat to the hair nearest the scalp where nits reside with these devices.

Mechanical Lice and Nit Removal: No matter what treatment one applies, combing nits out with specially designed nit combs is an essential part of effective treatment. Careful, systematic hair combing not only allows removal of lice and nits, but provides an opportunity to recheck for ongoing infestation. The problem with using this method exclusively is that it does not kill lice or louse eggs. The American Academy of Pediatrics (AAP) states in its guidelines for treating head lice that "manual removal of lice, in the absence of other treatment, is unlikely to be effective because lice may be difficult to find or may crawl away during the removal process."⁸ Neither adult lice

nor eggs live long once separated from the host. Adult lice can, however, reinfest the same person or be transmitted to another person if they contact the object harboring lice (e.g. comb, sofa, coat, headphones). Combing is not recommended as a first-line delousing method, as it is time consuming and rarely results in complete cure.

Combing is recommended as adjunct to use of an effective pediculicide. Effective treatment with any good pediculicide requires at least two treatments 5 to 7 days apart, to assure that both adult lice and eggs are killed by the treatment. Combing should follow both treatments to remove nits and dead lice and check for reinfestation.

The Centers for Disease Control and Prevention (CDC) state that "the most important step in treating a head lice infestation is to treat the person and other family members with head lice with medication to kill the lice."⁹

Recommended effective pediculicides are thoroughly described at <http://www.guideline.gov/guidelines/FTNGC-2451.html>, and summarized as follows:

1. Use of pyrethroid pediculicides: Permethrin and synergized pyrethrin both kill non-resistant crawling lice, but synergized pyrethrin is significantly more ovicidal than permethrin.¹⁰ Treatment failures are common with the pyrethroids due to emergence of resistant strains.¹¹
2. If treatment with over-the-counter pyrethroids is unsuccessful or the child cannot be treated with these products, prescription products, lindane or malathion may be used.
3. Combing: The use of a nit comb daily for two weeks is often recommended.

Regardless of what treatment you choose, the most important "rules" to follow when trying to cure head lice are:

1. Safety.
2. Follow the product instructions exactly as written.
3. Retreat in 5-7 days (one treatment will not cure).
4. Comb daily for 2 weeks to remove lice and nits.
5. Be patient and persistent.
6. Follow-up with a professional (nurse or physician) to confirm cure.

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LIBRARY OF LICE: Fall 2006

<http://www.headliceinfo.com>
 American Head Lice Information and Resource Center
www.cdc.gov/ncidod/dpd/parasites/headlice/default.htm
 CDC, Parasitic Disease Information
www.hsph.harvard.edu/headlice.html
 Laboratory of Public Health Entomology
 Harvard School of Public Health
 To obtain free lice kits,
 visit www.lindane4lice.com or call 1-877-786-7542.

See accompanying full prescribing information for Lindane Shampoo and Lindane Lotion.

NURSE'S notes

With the current variable enforcement of school no-nit policies, the school nurse must be prepared to facilitate maximum attendance of healthy, lice-free students, with or without nits. Stringent anti-lice procedures are a must. The following outlines areas to cover in a school lice eradication/prevention program:

School Nurse Responsibilities:

- Do a thorough whole school nit check four to five times a year (when kids return from breaks: summer, Thanksgiving, Christmas, winter and spring breaks).
- Stay current on the latest research on head lice.
- *Educate children and parents about head lice, treatment compliance and resources.*
- Be prepared; have a plan and information available ahead of time.
- Make sure people know to clean head phones, athletic headgear, etc.
- Help students keep their coats, hats, and other clothing separated.
- *Re-educate* if the outbreak is not cleared up within a reasonable period of time.

Explicit instructions to parents should include:

- How to identify and remove nits.
- Where to find nit-picking combs. How often to comb. When to comb. They may need a magnifying glass to see the nits.
- The most effective products to use to kill adult lice and eggs and how to use them.
- When to call a physician.
- Over the counter pediculicides – permethrin/synergized pyrethrins (NIX®, RID®, A-200®) according to package instructions are first line of treatment, followed by prescription pediculicides – Lindane Shampoo or malathion (OVIDE®) if OTC treatment fails.
- The error of using "alternative" remedies that do not kill lice.
- What to do when their first efforts fail – stressing accurate following of labeled treatment procedures, nit combing, and the safety ramifications of appropriate use of prescription pediculicides.
- Contact information for the school nurse.

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LINS 06-602

Alliant Pharmaceuticals
333 North Point Center, Suite 250
Alpharetta, GA 30022

Alliant Pharmaceuticals : Lindane Shampoo

Lindane SHAMPOO USP 1%

Lindane Shampoo is a highly effective
topical prescription product for head lice
that works in **JUST 4 MINUTES!**



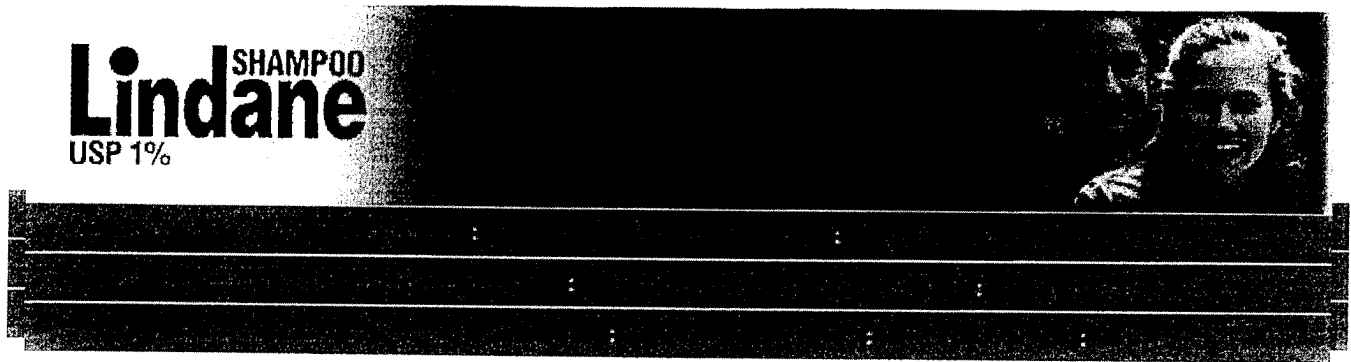
VISIT ALLIANTPHARMA.COM ONLINE



NOW AVAILABLE
IN SINGLE USE
2 oz BOTTLES!



Alliant Pharmaceuticals : About Lindane Shampoo



About Lindane Shampoo:

- Lindane Shampoo has been marketed for the topical treatment of head lice and pubic lice since 1947
- It has a fifty year history of being an effective treatment for head lice and pubic lice when used as directed by the FDA approved label.
- Lindane Shampoo has a FAST treatment time for head lice ... it works in just 4 MINUTES!
- Lindane Shampoo does not have an unpleasant odor
- Lindane Shampoo is not flammable and does not contain any alcohol or oils
- Lindane Shampoo is covered under most managed care and state Medicaid drug programs
- Lindane Shampoo is only available in a single-use 2 fluid ounce bottle

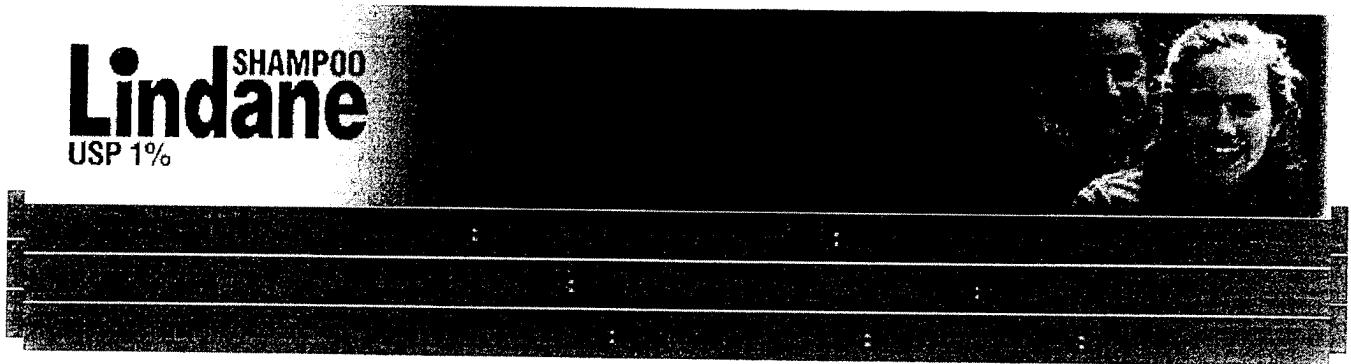
It is important that all patients and parents of patients adhere to the administration directions provided with each prescription of Lindane Shampoo.



[Lindane Shampoo Medication Instruction Guide](#)



Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents



Information for Patients and Parents:

[Overview of Head Lice](#) : [Tips on Removing Head Lice](#) : [Medication Treatment Guide](#)

Overview of Head Lice

Every day in the United States and the rest of the world, hundreds of people are infested with the parasite Head Lice (*Pediculus capitis*). In fact, head lice is the most common parasitic infestation to afflict humans.

The overwhelming majority of these infestations occur in children from 3 to 15 years of age. While there is no mortality associated with Head Lice, it does cause significant annoyance, embarrassment, and stress to the individual and the family.

Head lice (*Pediculus humanus capitis*) or head louse are small parasitic insects exquisitely adapted to living mainly on the scalp and neck hairs of their human host. The lice are **ectoparasites** that feed on human blood after piercing the skin and injecting their saliva. Head lice derive nutrient by blood-feeding once or more often each day. This feeding along with the saliva and feces may cause a localized allergic response mostly responsible for the intense itching. Mature lice are 3-4 mm long (approximately the size of a sesame seed). Their six impressive legs are elegantly evolved to grasp hair shafts and provide a striking example of biological specialization.

The head louse (*Pediculus humanus capitis*) and the body louse (*Pediculus humanus corporis*) are of similar size and can interbreed. The pubic louse (*Phthirus pubis*), or "crab," is **morphologically** distinct from the other two. The head louse is the most common of the three species and represents over 60% of all cases of human louse infestation.

Long associated with people, head lice have been recovered from prehistoric mummies. Head lice are equal opportunity parasites; they do not respect economic class distinctions. Their presence does not connote a lack of hygiene or sanitation practiced by their host.

Head lice are neither able to fly nor jump, lice are also unlikely to wander far from their preferred habitat. Lice and their eggs are unable to burrow into the scalp.

Lice are also called louse and sometimes referred to as cooties. Eggs are called **nits** and infested people as lousy. The infestation by head or body lice is termed **pediculiasis**, and the associated "disease" **pediculosis**. Delousing (more properly termed lousing) consists of any method for eliminating an infestation. Chemical treatments directed against lice are **pediculicides**. Those that kill adult and nymphal lice are sometimes called lousicides; those that kill the developing embryo within the egg are **ovicides**.

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Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents

Tips on Removing Head Lice

Treatment should be considered when active lice or viable eggs are observed. Itching of the scalp or the perception that something is crawling on the head does not mean you have lice or warrant treatment for lice. The first step toward treatment of head lice is to ensure that a correct diagnosis/identification has been made before considering treatment options. An old infestation, manifested solely by hatched eggs or continued itching of the skin or scalp, is not a cause for treatment. Treatment should be considered only when active lice, scabies or viable eggs are observed.

Once a bona-fide diagnosis of head lice or scabies has been confirmed it is then the decision of the healthcare provider to decide on what course of therapy for treatment.

Treatment of patients with head lice consists of two parts: Medication and Environmental Control Measures.

Medication: The goal of therapy is to eliminate the mite. There are several effective shampoos available to treat head lice. Lindane Shampoo is indicated for the treatment of head lice. Most treatments are highly effective at killing the nymphs and mature lice and less effective in killing the eggs or nits. It is important to follow the directions from the physician closely as in most cases these medications contain pesticides which if used or administered incorrectly may cause harm. Patients who are pregnant or breast feeding must alert their doctor as some products may not be suitable for their treatment. Drug therapy for head lice, when used appropriately, produces a cure rate in more than 90% of cases.

Environmental Control Measures: It is beneficial to launder all fomites (e.g., towels, pillow cases, sheets, hats, and children's stuffed animals) in hot water, followed by machine drying using the hottest cycle.

Temperatures exceeding 131 degrees Fahrenheit (55 degree Celsius) for more than 5 minutes will kill eggs, nymphs and mature lice.

Dry cleaning may be an effective alternative.

Combs and brushes can be treated by soaking them for more than 5 minutes in very hot water (>131 degrees F or 55 degrees C). Along with treatment of the hair and scalp all clothing, bedding and towels must be washed in hot water or dry cleaned.

Since adult lice cannot survive for long if they are separated from a host, and since eggs hatch in 6-10 days, carefully sealing potential fomites in plastic bags for 12-14 days can be effective. This technique works well for objects such as stuffed animals that do not tolerate laundering or dry cleaning.


Vacuuming selected areas of the home, including couches used by patients with infestation, is recommended by some as an adjunctive control measure.


Chemical insecticide sprays used in the home environment have not been shown to be effective in the control of head lice.

Chemical insecticide sprays used in the home environment have not been shown to be effective in the control of head lice.

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Medication Treatment Guide

 [English](#)

 [Spanish](#)

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Medication Instruction Guide

Lindane SHAMPOO
USP 1%

Prescription Lindane Shampoo USP, 1% is an effective prescription treatment to rid patients of head lice and crab lice. This second-line therapy is indicated in patients who cannot tolerate other approved therapies or when previous lice treatments have failed.

Read all instructions before using Lindane Shampoo.

It is imperative that instructions be followed carefully to ensure safe use. However, these basic instructions do not take the place of speaking with a physician. Use this product exactly as prescribed.

What to avoid

- Do not get Lindane Shampoo in the eyes. If this occurs, immediately rinse the eyes with water. Seek medical help if the eyes continue to hurt.
- If pregnant, do not use Lindane Shampoo or apply to others without first consulting a physician. If necessary, see "Proper use of gloves" below.
- Do not use oils on the skin or hair before or after using Lindane Shampoo. (Oils include oil-based hair products and conditioners.)

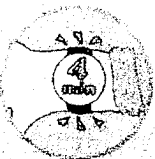
Proper use of gloves

- If applying Lindane Shampoo to self or others, only wear gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves.
- Continue to wear gloves until Lindane is completely washed out of hair.
- When finished, remove and dispose of gloves. Wash hands well.
- Make sure hair and skin on the head and neck are free from any residual shampoo, cream, or oils. (Oils can make Lindane Shampoo go through the skin faster and may increase the risk of seizure.)

Condition of hair

- Make sure hair is clean and dry.
- Use regular shampoo, without conditioner.
- Do not wash hair within 1 hour before use.

Applying Lindane Shampoo



- Shake bottle well.
- Use just enough Lindane Shampoo on dry hair to wet the hair and scalp.
- Do not add water to hair at this time.
- Also apply Lindane Shampoo to the short hairs at the back of the neck.
- Keep Lindane Shampoo on hair for 4 minutes.
- Do not wear a shower cap or any head covering at this time.
- Close the bottle with any leftover Lindane Shampoo and dispose in a trash container.
- Keep out of reach of children.

Removing Lindane Shampoo



- After 4 minutes, use a small amount of warm water to lather the Lindane Shampoo. (Hot water is not safe.)
- Once lather is created, wash Lindane Shampoo off the head.
- Avoid unnecessary contact of lather with other body surfaces.
- Do not leave any Lindane Shampoo on the head or hair. (Leaving shampoo on too long will not kill more of the lice and may continue to go through the skin, causing serious problems, such as seizures.)

After Lindane Shampoo use



- Dry hair with a towel.
- Use a special comb (called a nit comb) or tweezers to remove the dead nits (lice eggs) from hair. (It is best if another person performs this task.)
- All recently worn clothing, underwear, pajamas, hats, used sheets, pillow cases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Shampoo a second time. If lice are still present, consult a physician.
- If the patient continues to itch after Lindane Shampoo is used, it does not mean more Lindane Shampoo is needed. Even after all lice are dead, the skin may itch for a long time. Lindane Shampoo can sometimes worsen the itch. Talk with a physician about ways to soothe this itch.
- For complete instructions, consult a patient medication guide enclosed in each 2-oz bottle of Lindane Shampoo.

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-time treatment with safer medications for the treatment of head lice and crab lice.

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, individuals with other skin conditions (eg, atopic dermatitis, psoriasis), and those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of head lice and crab lice and is not necessarily an indication for retreatment with Lindane Shampoo.

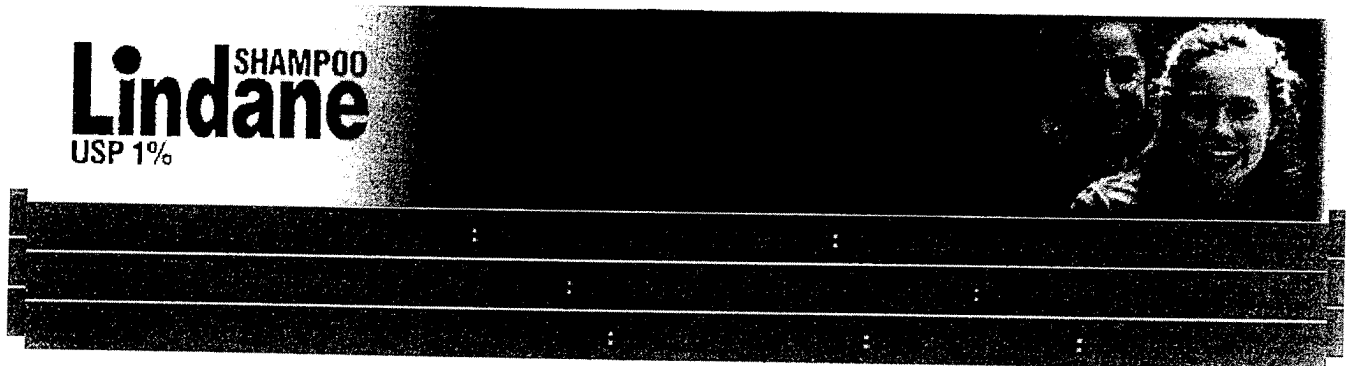
Lindane Shampoo has been reported to cause central nervous system stimulation ranging from dizziness to seizures. Although seizures were almost always associated with ingestion or misuse of the product (including repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported.

See accompanying full prescribing information.

ALLIANT
Pharmaceuticals, Inc.

Alliant Pharmaceuticals, Inc., www.alliantpharma.com
1-877-746-7542 www.lindane4lice.com ©2005 Alliant Pharmaceuticals, Inc. 108522-01G-01

Alliant Pharmaceuticals : Lindane Shampoo - Healthcare Professionals



Information for Healthcare Professionals:

Lindane Overview

Lindane Shampoo is a highly effective topical prescription product for head lice that works in **JUST 4 MINUTES!**

- Lindane Shampoo has been marketed for the topical treatment of head lice and pubic lice since 1947
- It has a fifty year history of being an effective treatment for head lice and pubic lice when used as directed by the FDA approved label.
- Lindane Shampoo has a FAST treatment time for head lice ... it works in just 4 MINUTES!
- Lindane Shampoo does not have an unpleasant odor
- Lindane Shampoo is not flammable and does not contain any alcohol or oils
- Lindane Shampoo is covered under most managed care and state Medicaid drug programs
- Lindane Shampoo is only available in a single-use 2 fluid ounce bottle.

Important Safety Information

WARNINGS:

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE section of the full prescribing information.) Lindane Lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies. (SEE INDICATIONS AND USAGE section of the full prescribing information.)

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Shampoo and Lotion use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo and Lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (eg, atopic dermatitis, psoriasis) and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.


Contraindication

Lindane Shampoo and Lotion are contraindicated in premature infants and individuals with known controlled seizure disorders.

Proper Use

Instruct patients on proper use of Lindane Shampoo and Lotion, the amount to apply, how long to have it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and it is not necessarily an indication for retreatment with Lindane Shampoo or Lotion. (SEE DOSAGE AND ADMINISTRATION sections of the full prescribing information.)

Full Prescribing Information

 [Please click here to download full prescribing information.](#)

Alliant Pharmaceuticals : Lindane Shampoo - Healthcare Professionals



Lindane is a fast and effective treatment for lice and scabies when used as labeled

NOW AVAILABLE ONLY IN 2oz. SINGLE-USE BOTTLES

Lindane

USP 1% SHAMPOO/LOTION

FAST TREATMENT TIME FOR HEAD LICE AND SCABIES

Lindane Shampoo USP 1% is indicated for the treatment of head lice, crab lice, and their ova in patients who cannot tolerate other approved therapies, or who have failed treatment with other therapies. Recommended treatment time is just **FOUR MINUTES**. Lindane Shampoo has shown an efficacy rate of 92% at seven days and 85% at fourteen days¹.

Lindane Lotion USP 1% is indicated for the treatment of scabies in patients who cannot tolerate other approved therapies, or who have failed treatment with other therapies. Recommended minimum treatment time is just **EIGHT HOURS**. Lindane Lotion has shown an efficacy rate of 86%².

Ready-to-dispense, child-proof, single-use bottle with medication guide attached

PRODUCT	SIZE/PKG	NDC#
Lindane Shampoo USP 1%	2 fl oz (60mL)	68188-931-90
Lindane Lotion USP 1%	2 fl oz (60mL)	68188-935-90

See black box warning regarding proper use, contraindications, and neurotoxicity.

Extensive sales promotions and product support by a dedicated sales force begins immediately - place your order with your wholesaler today.

For more information, please call 1-877-786-7542 or visit www.lindane4lice.com and www.lindane4scabies.com



¹ Brandenburg K, Deimard AS, DiNapoli J, et al. 1% permethrin cream rinse vs 1% lindane shampoo in treating Pediculosis capitis. Am J Dis Child. 1986;140(9):894-896. ² Schultz MW, Gomez M, Hansen RC, et al. Comparative study of 5% permethrin cream and 1% Lindane Lotion for the treatment of scabies. Arch Dermatol. 1990; 126:167-170.

See accompanying full prescribing information.

LIN 241

LINDANE SHAMPOO, USP 1% Rx only

WARNING:
Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with other medications for the treatment of lice. (See INDICATIONS AND USAGE.)

Neurotoxic Effects

Symptoms and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also after a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly and individuals with other skin conditions and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Contraindications

Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders. **Precaution:** Contact patients on prior use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for re-treatment with Lindane Shampoo. (See DOSAGE AND ADMINISTRATION.)

DESCRIPTION

Lindane Shampoo, USP 1%, is an organochloride and is active against Pediculosis humanus capitis (head lice), Phthirus pubis (crab lice) and their ova by action on the active ingredient. It contains triethanolamine lauryl sulfate, polysorbate 80, hydrochloric acid, acetone and purified water to form a shampoo base. The pH may be adjusted with 10% hydrochloric acid solution and/or 10% sodium hydroxide solution. Lindane is the gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane having the following structural formula:



C₆H₆Cl₆

CLINICAL PHARMACOLOGY

Lindane exerts its parasitocidal action by being directly absorbed into the parasites and their ova. Friedman and Mabbitt reported approximately 10% absorption of a lindane acetone solution applied to the forearm of human subjects and left in place for 24 hours. This vehicle was different from the approved product and the insignificant penetration of lindane is dependent on the vehicle. Therefore, the clinical significance of these observations is unknown. (See also reported blood level of 780 ng/mL associated with convulsions following the topical application of a lindane-containing product. Following a minor peak blood level of 28 ng/mL 6 hours after total body application of Lindane Lotion to scabies in infants and children. The half-life in blood was determined to be 18 hours. Data available in the literature suggest that lindane has a rapid distribution phase followed by a longer 18 elimination phase.)

There are no clinical dose ranging studies for Lindane Shampoo.

INDICATIONS AND USAGE

Lindane Shampoo is indicated for the treatment of head lice (infestations of Pediculosis humanus capitis), crab lice (infestations of Phthirus pubis), and their ova only in patients who:

1. cannot tolerate other approved therapies; or
2. have failed treatment with other approved therapies.

Lindane Shampoo should be used in the context of an overall lice management program that includes:

- Visual inspection to ensure that the patient is currently infested with lice (completely dry hair or "nits") can remain on hair shaft long after use of treatment.
- Manual removal of nits using a comb designed for this purpose and/or individual removal with tweezers followed by close examination of the hair and scalp.
- Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Shampoo only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry cleaned.

Carriers applying this product to patients should wear gloves less permeable to Lindane (such as nitrile, latex with neoprene or clear vinyl), and thoroughly clean hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.

Lindane Shampoo does not prevent relaxation or reinfestation and should not be used to ward off a possible infestation.

CONTRAINDICATIONS

Lindane Shampoo is contraindicated for premature infants because they absorb it more permeable than that of full-term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane. Lindane Shampoo is also contraindicated for patients with known (phenotypic) seizure and other skin conditions (e.g. atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.

Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

WARNINGS (See below WARNINGS)

Symptoms and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions.

There have been cases of adverse events reported for Lindane Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred in approximately 20% of these cases. The shampoo and lotion were reported to have been used according to the labeled directions. Of these cases, thirteen

deaths were reported, many of which were female from the time of sexual Lindane use. Lindane toxicity, verified by autopsy, was the cause of one infant's death and was the cause of death reported for an adult in a secondary source. For these causes of death for the other cases were attributed to reasons other than Lindane. Most of these adverse events occurred with Lindane Lotion.

Infants, children, the elderly and individuals with other skin conditions and those who weigh < 110 lbs (50 kg) may be at a greater risk of serious neurotoxicity (see Pediatric Use and Geriatric Use). Animal studies have shown increased susceptibility to neurologic damage in young animals. Children have a larger body surface area to volume ratio that may result in a proportionally larger systemic exposure.

Careful consideration should be given before prescribing Lindane Shampoo in patients with conditions that may increase the risk of seizure such as HIV infection, history of head trauma or a prior seizure. CNS tumor, the presence of severe hepatic/renal impairment, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold (see PRECAUTIONS: Drug Interactions).

Patients should be instructed on the proper use of Lindane Shampoo, especially the amount to apply, how long to leave shampoo on, and the need to avoid re-treatment. Patients should be informed that itching may occur after the successful killing of lice and repeat treatment may not be necessary.

A Lindane Shampoo Medication Guide must be given to the patient each time Lindane Shampoo is dispensed, as required by law.

PRECAUTIONS

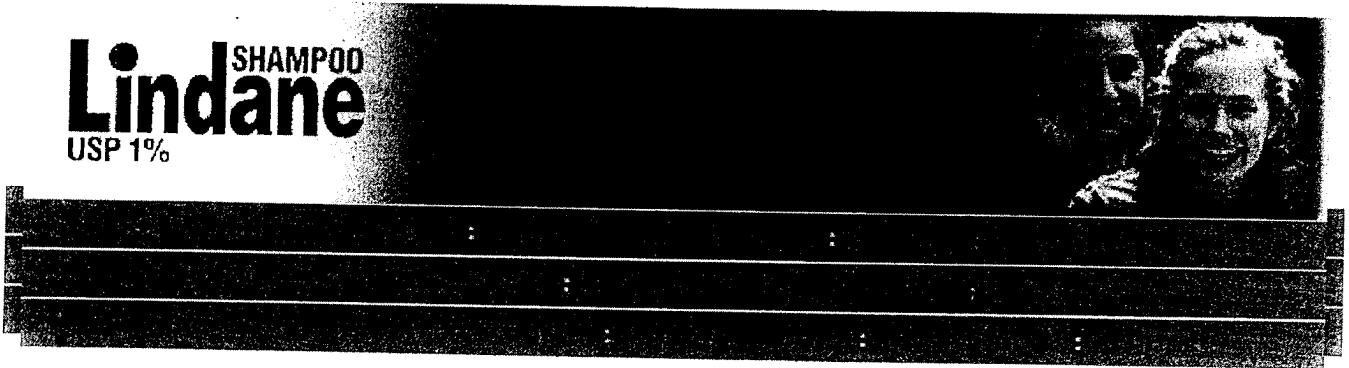
General: Care should be taken to avoid contact with the eyes. If such contact occurs, eyes should be immediately flushed with water. If irritation or sensitization occurs, the patient should be referred to a physician.

Information for Patients (and Caregivers):

- This product can be poisonous if misused.
- Other important information is found in the Medication Guide, which by law, must be dispensed with Lindane Shampoo.
- If putting Lindane Shampoo on another person, the person applying shampoo should wear less permeable gloves (such as nitrile, latex with neoprene or clear vinyl), and thoroughly clean their hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.
- If the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible.
- If the patient could be pregnant, other treatments may be preferable.
- Use Lindane Shampoo for lice only.
- The use of oil treatments, oil based hair dressings or conditioners immediately before and after applying Lindane Shampoo should be avoided. Oil can make the Lindane Shampoo go through the skin faster and possibly increase the risk of neurotoxicity (e.g., seizures).
- Information for Use

- MGP002272

Alliant Pharmaceuticals : Lindane Shampoo - Important Safety Information



Important Safety Information:

WARNINGS

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE section of the full prescribing information.)

Neurologic Toxicity

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Contraindications

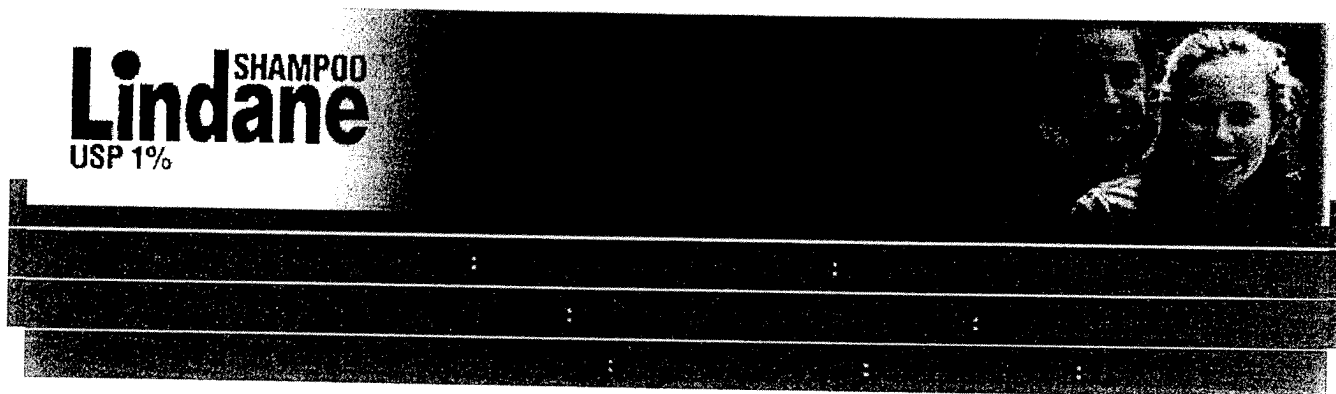
Lindane Shampoo is contraindicated in premature infants and individuals with known controlled seizure disorders.

Proper Use

Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to have it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and it is not necessarily an indication for retreatment with Lindane Shampoo. (SEE DOSAGE AND ADMINISTRATION sections of the full prescribing information.)



Alliant Pharmaceuticals : Lindane Shampoo - Contact Us



Contact Us :

Mailing Address: Alliant Pharmaceuticals, Inc.
333 North Point Center East Suite 250
Alpharetta, Georgia 30022

Phone: 770.817.4500

You may also direct any comments or questions to us using the following form:



Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents

Lindane SHAMPOO
USP 1%



Information for Patients and Parents:

[Overview of Head Lice](#) : [Tips on Removing Head Lice](#) : [Medication Treatment Guide](#)

Overview of Head Lice

Every day in the United States and the rest of the world, hundreds of people are infested with the parasite Head Lice (*Pediculus capitis*). In fact, head lice is the most common parasitic infestation to afflict humans.

The overwhelming majority of these infestations occur in children from 3 to 15 years of age. While there is no mortality associated with Head Lice, it does cause significant annoyance, embarrassment, and stress to the individual and the family.

Head lice (*Pediculus humanus capitis*) or head louse are small parasitic insects exquisitely adapted to living mainly on the scalp and neck hairs of their human host. The lice are **ectoparasites** that feed on human blood after piercing the skin and injecting their saliva. Head lice derive nutrient by blood-feeding once or more often each day. This feeding along with the saliva and feces may cause a localized allergic response mostly responsible for the intense itching. Mature lice are 3-4 mm long (approximately the size of a sesame seed). Their six impressive legs are elegantly evolved to grasp hair shafts and provide a striking example of biological specialization.

The head louse (*Pediculus humanus capitis*) and the body louse (*Pediculus humanus corporis*) are of similar size and can interbreed. The pubic louse (*Phthirus pubis*), or "crab," is **morphologically** distinct from the other two. The head louse is the most common of the three species and represents over 60% of all cases of human louse infestation.

Long associated with people, head lice have been recovered from prehistoric mummies. Head lice are equal opportunity parasites; they do not respect economic class distinctions. Their presence does not connote a lack of hygiene or sanitation practiced by their host.

Head lice are neither able to fly nor jump, lice are also unlikely to wander far from their preferred habitat. Lice and their eggs are unable to burrow into the scalp.

Lice are also called louse and sometimes referred to as cooties. Eggs are called **nits** and infested people as lousy. The infestation by head or body lice is termed **pediculiasis**, and the associated "disease" **pediculosis**. Defousing (more properly termed lousing) consists of any method for eliminating an infestation. Chemical treatments directed against lice are **pediculicides**. Those that kill adult and nymphal lice are sometimes called lousicides; those that kill the developing embryo within the egg are **ovicides**.

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Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents

Tips on Removing Head Lice

Treatment should be considered when active lice or viable eggs are observed. Itching of the scalp or the perception that something is crawling on the head does not mean you have lice or warrant treatment for lice. The first step toward treatment of head lice is to ensure that a correct diagnosis/identification has been made before considering treatment options. An old infestation, manifested solely by hatched eggs or continued itching of the skin or scalp, is not a cause for treatment. Treatment should be considered only when active lice, scabies or viable eggs are observed.

Once a bona-fide diagnosis of head lice or scabies has been confirmed it is then the decision of the healthcare provider to decide on what course of therapy for treatment.

Treatment of patients with head lice consists of two parts: Medication and Environmental Control Measures.

Medication: The goal of therapy is to eliminate the mite. There are several effective shampoos available to treat head lice. Lindane Shampoo is indicated for the treatment of head lice. Most treatments are highly effective at killing the nymphs and mature lice and less effective in killing the eggs or nits. It is important to follow the directions from the physician closely as in most cases these medications contain pesticides which if used or administered incorrectly may cause harm. Patients who are pregnant or breast feeding must alert their doctor as some products may not be suitable for their treatment. Drug therapy for head lice, when used appropriately, produces a cure rate in more than 90% of cases.

Environmental Control Measures: It is beneficial to launder all fomites (e.g., towels, pillow cases, sheets, hats, and children's stuffed animals) in hot water, followed by machine drying using the hottest cycle.

Temperatures exceeding 131 degrees Fahrenheit (55 degree Celsius) for more than 5 minutes will kill eggs, nymphs and mature lice.

Dry cleaning may be an effective alternative.

Combs and brushes can be treated by soaking them for more than 5 minutes in very hot water (>131 degrees F or 55 degrees C). Along with treatment of the hair and scalp all clothing, bedding and towels must be washed in hot water or dry cleaned

Since adult lice cannot survive for long if they are separated from a host, and since eggs hatch in 6-10 days, carefully sealing potential fomites in plastic bags for 12-14 days can be effective. This technique works well for objects such as stuffed animals that do not tolerate laundering or dry cleaning.

Vacuuming selected areas of the home, including couches used by patients with infestation, is recommended by some as an adjunctive control measure.


Chemical insecticide sprays used in the home environment have not been shown to be effective in the control of head lice.

Chemical insecticide sprays used in the home environment have not been shown to be effective in the control of head lice.

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Medication Treatment Guide

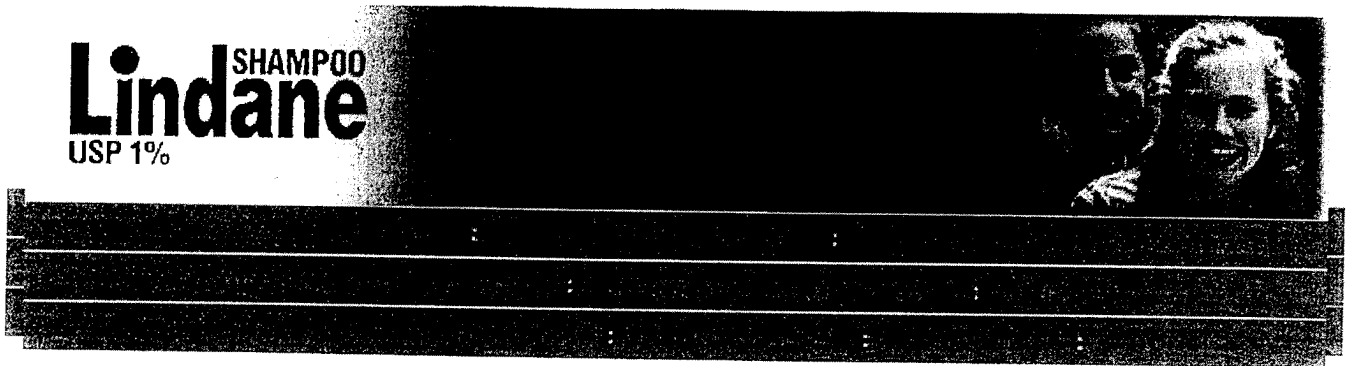
 [English](#)

 [Spanish](#)

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Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents



Information for Patients and Parents:

Overview of Head Lice : Tips on Removing Head Lice : Medication Treatment Guide

Overview of Head Lice

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Alliant Pharmaceuticals : Lindane Shampoo - Patients and Parents

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Medication Treatment Guide

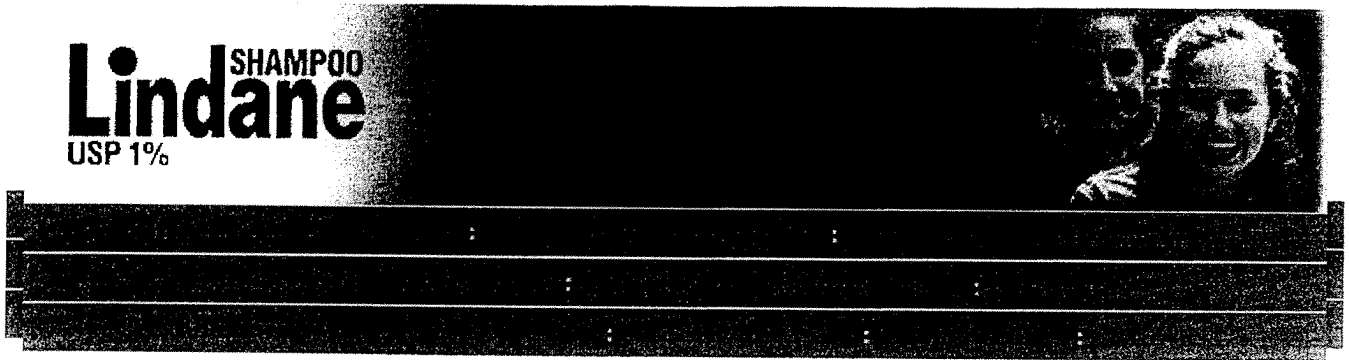
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Alliant Pharmaceuticals : Lindane Shampoo - Healthcare Professionals



Information for Healthcare Professionals:

Lindane Overview

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- Lindane Shampoo has been marketed for the topical treatment of head lice and pubic lice since 1947
- It has a fifty year history of being an effective treatment for head lice and pubic lice when used as directed by the FDA approved label.
- Lindane Shampoo has a FAST treatment time for head lice ... it works in just 4 MINUTES!
- Lindane Shampoo does not have an unpleasant odor
- Lindane Shampoo is not flammable and does not contain any alcohol or oils
- Lindane Shampoo is covered under most managed care and state Medicaid drug programs
- Lindane Shampoo is only available in a single-use 2 fluid ounce bottle

Important Safety Information

WARNINGS:

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE section of the full prescribing information.) Lindane Lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies. (SEE INDICATIONS AND USAGE section of the full prescribing information.)

Neurologic Toxicity

Seizures and deaths have been reported following Lindane Shampoo and Lotion use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo and Lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (eg, atopic dermatitis, psoriasis) and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

Contraindication

Lindane Shampoo and Lotion are contraindicated in premature infants and individuals with known controlled seizure disorders.

Proper Use

Instruct patients on proper use of Lindane Shampoo and Lotion, the amount to apply, how long to have it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and it is not necessarily an indication for retreatment with Lindane Shampoo or Lotion. (SEE DOSAGE AND ADMINISTRATION sections of the full prescribing information.)

Full Prescribing Information



[Please click here to download full prescribing information.](#)

Alliant Pharmaceuticals : Lindane Shampoo - Healthcare Professionals



EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MORTON GROVE PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	No.: 08-C-1384
)	
v.)	Judge Bucklo
)	Magistrate Judge Mason
THE NATIONAL PEDICULOSIS)	
ASSOCIATION, INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	
)	

**DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S
RESPONSE TO MORTON GROVE PHARMACEUTICALS, INC.'S
SECOND SET OF REQUESTS FOR ADMISSION**

Defendant the National Pediculosis Association, Inc. ("NPA") respectfully responds and objects to Plaintiff's Second Set of Requests for Admission as follows:

General Objections

1. NPA objects to Morton Grove's Definitions and Instructions to the extent they seek to impose obligations different from, in addition to, or inconsistent with those imposed by the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or any other applicable Local Rules or Standing Orders.

2. NPA objects to Instruction Number 5, and specifically to the definitions of the terms "NPA," "You" and "Your," because they are overly broad and seek information that is neither relevant to this matter nor reasonably calculated to lead to the discovery of admissible evidence. As a non-profit 501(c)(3) organization, NPA has no parents, subsidiaries or divisions. NPA will define these terms to mean the National Pediculosis Association, its predecessors, affiliates, officers, directors, and employees.

3. NPA objects to the Requests for Admission to the extent they seek discovery beyond that permitted by the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or any other applicable Local Rules or Standing Orders.

4. NPA objects to the Requests for Admission on the basis that they are vague, ambiguous, or overly broad.

5. NPA objects to the Requests for Admission to the extent they seek disclosure of information that is protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege, doctrine, or immunity from discovery.

6. NPA objects to the Requests for Admission to the extent they seek disclosure of information not in NPA's possession, custody, or control; seeks disclosure of information already in Morton Grove's possession, custody, or control; or seeks disclosure of information equally available to Morton Grove.

7. NPA objects to the Requests for Admission to the extent they assume, imply, or require any legal conclusions.

8. NPA objects to the Requests for Admission to the extent they seek disclosure of information that is not relevant to the issues in this proceeding or that is not reasonably calculated to lead to the discovery of admissible evidence. By responding to any of Morton Grove's Requests for Admission, NPA does not concede the relevance thereof to the subject matter of this litigation.

9. In making these objections and responses herein, NPA does not in any way waive or intend to waive but, to the contrary, intends to preserve and is preserving:

a. all objections as to authenticity, competency, relevancy, materiality, privilege, and admissibility as to the information provided, or the subject matter thereof;

b. all rights to object on any ground to the use of the information provided, any evidence supporting the information provided, or the subject matter thereof in any subsequent proceeding, including any trial in this or any other action;

c. all rights to object on any ground at any time to other interrogatories, requests for the production of documents and things, requests for admission, or other discovery involving the information provided or any evidence supporting the information provided.

10. NPA expressly reserves the right to supplement or modify its objections and responses to the Requests for Admission based on the results of NPA's continuing investigation and discovery in this proceeding.

11. These General Objections are incorporated by reference into each of the specific responses below as if fully set forth therein.

Specific Objections and Responses to Requests for Admission

1. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer to Dr. Tor Shwayder.

RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about "surveys, polls, or similar studies of doctors that refer to Dr. Tor Shwayder" without respect to whether these "surveys, polls, or similar studies of doctors" relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA's Counterclaim with respect to Dr. Shwayder is whether the specific statements identified in the Counterclaim as

contained in Dr. Shwayder's letter, and subsequently posted to www.lindane.com and www.lindanetruth.com by Morton Grove, constitute false or misleading advertising that has injured or is likely to injure NPA. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA's Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase "surveys, polls, or similar studies of doctors" contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase "surveys, polls, or similar studies of doctors" to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA's counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to the false or misleading statements contained in a letter from Dr. Tor Shwayder and posted on www.lindane.com and www.lindanetruth.com by Morton Grove. NPA further admits that, at this point in the litigation, it has not conducted surveys, polls, or studies of doctors that refer to Dr. Shwayder. Except as expressly admitted herein, NPA denies this Request.

2. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer to Dr. Adelaide Hebert.

RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about "surveys, polls, or similar studies of doctors that refer to Dr. Adelaide Hebert" without respect to whether these "surveys, polls, or similar studies

of doctors” relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA’s Counterclaim with respect to Dr. Hebert is whether the specific statements identified in the Counterclaim as contained in Dr. Hebert’s letter, and subsequently posted to www.lindane.com and www.lindanetruth.com by Morton Grove, constitute false or misleading advertising that has injured or is likely to injure NPA. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA’s Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase “surveys, polls, or similar studies of doctors” contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase “surveys, polls, or similar studies of doctors” to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA’s counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to the false or misleading statements contained in a letter from Dr. Adelaide Hebert and posted on www.lindane.com and www.lindanetruth.com by Morton Grove. NPA further admits that, at this point in the litigation, it has not conducted surveys, polls, or studies of doctors that refer to Dr. Hebert. Except as expressly admitted herein, NPA denies this Request.

3. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer to Dr. Chang Lee.

RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about “surveys, polls, or similar studies of doctors that refer to Dr. Chang Lee” without respect to whether these “surveys, polls, or similar studies of doctors” relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA’s Counterclaim with respect to Dr. Lee is whether the specific statements identified in the Counterclaim as contained in Dr. Lee’s letters constitute false or misleading advertising that has injured or is likely to injure NPA. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA’s Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase “surveys, polls, or similar studies of doctors” contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase “surveys, polls, or similar studies of doctors” to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA’s counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to the false or misleading statements contained in letters from Dr. Chang Lee as Morton Grove’s former vice president of regulatory affairs and clinical research. NPA further admits that, at this point in the litigation, it has not

conducted surveys, polls, or studies of doctors that refer to Dr. Lee. Except as expressly admitted herein, NPA denies this Request.

4. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer to Morton Grove, lindane, Lindane lotion or Lindane Shampoo.

RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about “surveys, polls, or similar studies of doctors that refer to Morton Grove, lindane, Lindane [L]otion or Lindane Shampoo” without respect to whether these “surveys, polls, or similar studies of doctors” relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA’s Counterclaim is whether the specific Morton Grove statements identified in the Counterclaim constitute false or misleading advertising that has injured or is likely to injure NPA. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA’s Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase “surveys, polls, or similar studies of doctors” contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase “surveys, polls, or similar studies of doctors” to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA’s counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to Morton Grove’s

false or misleading statements referring to lindane, Lindane Lotion, or Lindane Shampoo. NPA further admits that, at this point in the litigation, it has not conducted surveys, polls, or studies of doctors that refer to Morton Grove, Lindane Lotion, or Lindane Shampoo. NPA also admits that throughout its history, it has regularly communicated with a variety of individuals, including doctors and other health professionals, about lice and scabies treatments, including but not limited to those containing the chemical lindane. NPA admits that these interactions included gathering information about the chemical lindane and products containing lindane from various sources, including but not limited to physicians. NPA further admits that through its websites, www.headlice.org, it has collected information about lice and scabies treatments, including but not limited to those containing the chemical lindane, from the general public, which population may have included doctors. Except as expressly admitted herein, NPA denies this Request.

5. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer to any material that was and/or is available via the website www.lindane.com (or www.lindanetruth.com).

RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about “surveys, polls, or similar studies of doctors that refer to any material that was and/or is available via the website www.lindane.com (or www.lindanetruth.com)” without respect to whether these “surveys, polls, or similar studies of doctors” relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA’s Counterclaim is whether the specific Morton Grove statements identified in the Counterclaim, not the whole websites, constitute false or misleading advertising that has injured or is likely to injure NPA, and polls or studies related to general material found on the websites would be designed to elicit opinion or anecdotal

information that would be irrelevant to the truth or falsity of Morton Grove's statements. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA's Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase "surveys, polls, or similar studies of doctors" contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase "surveys, polls, or similar studies of doctors" to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA's counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to Morton Grove's false or misleading statements referring to lindane, Lindane Lotion, or Lindane Shampoo. NPA further admits that, at this point in the litigation, it has not conducted surveys, polls, or studies of doctors that refer to specific material or statements posted on www.lindane.com and/or www.lindanetruth.com. Except as expressly admitted herein, NPA denies this Request.

6. Admit the NPA has conducted no surveys, polls, or similar studies of doctors that refer or relate to Morton Grove's www.lindane.com (or www.lindanetruth.com) website in any manner.

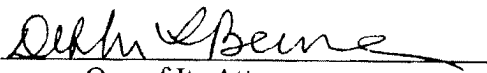
RESPONSE: In addition to and without waiving the foregoing General Objections, NPA objects to this Request on the ground that it is irrelevant and not related to the subject matter of this litigation because it seeks information about "surveys, polls, or similar studies of doctors that refer or relate to Morton Grove's www.lindane.com (or www.lindanetruth.com)

website in any manner” without respect to whether these “surveys, polls, or similar studies of doctors” relate to any claim, defense, or statement at issue in this lawsuit. In particular, NPA objects to this Request because what is at issue in NPA’s Counterclaim is whether the specific Morton Grove statements identified in the Counterclaim, not the whole websites, constitute false or misleading advertising that has injured or is likely to injure NPA, and polls or studies related to general material found on the websites would be designed to elicit opinion or anecdotal information that would be irrelevant to the truth or falsity of Morton Grove’s statements. NPA also objects to this Request as assuming facts not in evidence to the extent it assumes doctors are the only target or the relevant target of the misleading Morton Grove statements identified in NPA’s Counterclaim. Thus, NPA objects to this Request on the ground that it seeks to impose discovery obligations on NPA that are inconsistent with the Federal Rules of Civil Procedure, the Rules of the United States District Court for the Northern District of Illinois, or other applicable Local Rules or Standing Orders. NPA also objects to this Request because the phrase “surveys, polls, or similar studies of doctors” contains undefined terms and is therefore vague and ambiguous. NPA will define the phrase “surveys, polls, or similar studies of doctors” to mean formal surveys or polls of doctors who may prescribe lice or scabies treatments. Subject to and without waiving the foregoing objections and the General Objections, NPA responds as follows: NPA admits that prior to filing NPA’s counterclaim against Morton Grove, it and its counsel conducted a reasonable inquiry as to Morton Grove’s false or misleading statements posted on www.lindane.com and www.lindanetruth.com. NPA further admits that, at this point in the litigation, it has not conducted surveys, polls, or studies of doctors that refer or relate to either of Morton Grove’s websites, www.lindane.com and www.lindanetruth.com. Except as expressly admitted herein, NPA denies this Request.

Dated: August 4, 2008

Respectfully Submitted,

THE NATIONAL PEDICULOSIS
ASSOCIATION, INC.

By: 
One of Its Attorneys

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CERTIFICATE OF SERVICE

I, April A. Otterberg, an attorney, hereby certify that on this 4th day of August, 2008, I caused a copy of **DEFENDANT THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S RESPONSE TO PLAINTIFF'S SECOND SET OF REQUESTS FOR ADMISSION** to be served by email and U.S. Mail, postage pre-paid, upon the following:

William C. O'Neil
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601
Telephone: 312-558-5600

Attorney for Plaintiff Morton Grove Pharmaceuticals, Inc.

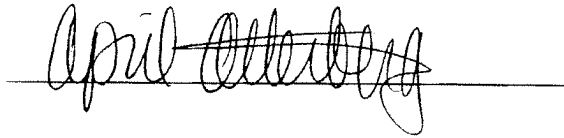


EXHIBIT C

Chapter 4 ADVISORY ACTIONS

This chapter defines and establishes uniform guidance and procedures for Warning Letters and Untitled Letters.

This chapter includes the following sections:

Section	Topic	Page
4-1	WARNING LETTERS	4-1
4-1-1	Warning Letter Procedures	4-1
4-1-2	Warning Letters To Government Agencies	4-3
4-1-3	Issuing Warning Letters - Factors to Consider	4-4
4-1-4	Center Concurrence And Letters Issued By Centers	4-6
4-1-5	Letters For Illegal Promotional Activities	4-10
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4-1-8	Warning Letter Follow-Up	4-11
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4-1-11	Warning Letter Distribution	4-15
4-1-12	Warning and Untitled Letters Addressed to Importers, Customs Brokers, and Foreign Firms	4-16
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4-1-14	Center For Biologics Evaluation And Research (CBER)	4-18
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4-1-16	Center For Devices And Radiological Health (CDRH)	4-23
4-1-17	Center For Food Safety And Applied Nutrition (CFSAN)	4-25
4-1-18	Tracking	4-25
4-2	UNTITLED LETTERS	4-25
4-2-1	Policy	4-25
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4-1 WARNING LETTERS

4-1-1 Warning Letter Procedures

When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the Food and Drug Administration's (FDA's) practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action. Warning Letters are issued to achieve voluntary compliance and to establish prior notice. (Prior notice is discussed in Chapter 10.) The use of Warning Letters and the prior notice policy are based on the expectation that most individuals and firms will voluntarily comply with the law.

The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if

not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act).

The Warning Letter was developed to correct violations of the statutes or regulations. Also available to the agency are enforcement strategies which are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/or prosecution to achieve correction. Despite the significance of the violations, there are some circumstances that may preclude the agency from taking any further enforcement action following the issuance of a Warning Letter. For example, the violation may be serious enough to warrant a Warning Letter and subsequent seizure; however, if the seizable quantity fails to meet the agency's threshold value for seizures, the agency may choose not to pursue a seizure. In this instance, the Warning Letter would document prior warning if adequate corrections are not made and enforcement action is warranted at a later time.

Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. Under the law such individuals are presumed to be fully aware of their responsibilities. Consequently, responsible individuals should not assume that they would receive a Warning Letter, or other prior notice, before FDA initiates enforcement action.

FDA is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action, except in a few specifically defined areas. When acting under the authority of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Act, FDA is required by law to provide a written notification to manufacturers when the agency discovers products that fail to comply with a performance standard or that contain a radiation safety defect. Because of the legal requirements of Subchapter C, minor variations in the procedures may occur.

A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.

There are instances when issuing a Warning Letter is not appropriate, and, as previously stated, a Warning Letter is not a prerequisite to taking enforcement action. Examples of situations where the agency will take enforcement action without necessarily issuing a Warning Letter include:

1. The violation reflects a history of repeated or continual conduct of a similar or substantially similar nature during which time the individual and/or firm has been notified of a similar or substantially similar violation;
2. The violation is intentional or flagrant;
3. The violation presents a reasonable possibility of injury or death;
4. The violations, under Title 18 U.S.C. 1001, are intentional and willful acts that once having occurred cannot be retracted. Also, such a felony violation does not require prior notice. Therefore, Title 18 U.S.C. 1001 violations are not suitable for inclusion in

Warning Letters; and,

5. When adequate notice has been given by other means and the violations have not been corrected, or are continuing. See Chapter 10, Prior Notice, for other methods of establishing prior notice.

In certain situations, the agency may also take other actions as an alternative to, or concurrently with, the issuance of a Warning Letter. For example:

1. The product is adulterated under Section 402(a)(3) or 402(a)(4) of the Act;
2. There is a violation of CGMP;
3. The product contains illegal pesticide residues; or
4. The product shows short contents, subpotency, or superpotency.

Additional instructions for Warning Letters in specific product areas are found in compliance program guidance and in compliance policy guides.

Also, see Exhibit 4-1, the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures. Developed to facilitate review of all Warning Letters and Untitled Letters by the Office of Chief Counsel (OCC), the procedures provide instructions for submitting such letters to OCC, and include timeframes and routing information.

4-1-2 Warning Letters To Government Agencies

Government establishments should be held to the same standards as nongovernment establishments. The public health standards are identical; however, the method used to ensure compliance with these standards may vary. FDA believes that government establishments will achieve and maintain a higher rate of voluntary compliance with FDA regulations compared with nongovernment establishments. Efforts to obtain voluntary compliance should be made and documented before recommending the issuance of a Warning Letter. These efforts may include discussing the violations with the responsible government officials by phone or in a meeting, recommending an Untitled Letter, or requesting a written corrective action plan and periodic progress reports. The government establishment's progress should be monitored and a follow-up inspection should be scheduled, within a reasonable time consistent with the noted violations to confirm correction of the violations.

Whenever significant violations are observed at a government establishment, or if attempts to achieve compliance have been ineffective, the district (or center) should arrange a meeting with OE, OCC, and the relevant center to determine a strategy to achieve timely and effective compliance. The meeting should include ORO/DFSR if the government establishment is a state or local agency.

Also, see Exhibit 4-1, the agency's "Procedures for Clearing FDA Warning Letters and Untitled Letters." All agency components responsible for issuing Warning Letters and Untitled Letters must follow these procedures.